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PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(c).

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INVENTOR(s) APPLICANT(s)			
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)
Gamada	Kazuyoshi		Aurora, CO 80017

TITLE OF THE INVENTION (280 characters max)

"Non-Surgically Correcting Abnormal Knee Loading: Treatment and Training Equipment"

CORRESPONDENCE ADDRESS

GREENLEE, WINNER AND SULLIVAN, P.C.
5370 Manhattan Circle, Suite 201
Boulder, CO 80303 USA
Phone: (303) 499-8080; Fax (303) 499-8089; Email: winner@Greenwin.com

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NON-SURGICALLY CORRECTING ABNORMAL KNEE LOADING: TREATMENT AND TRAINING EQUIPMENT

FIELD OF INVENTION

This invention is in the field of training and treatment equipment, and methods to reduce and correct abnormal knee loading using this equipment.

BACKGROUND OF THE INVENTION

The knee is composed of three bones, the patella (knee cap), the femur and the tibia. The meniscus (cartilage), composed of the lateral and medial menisci, cushion and distribute the weight of the femur uniformly across the joint. The gaps between the tibia and femur on the inside and outside of the knee are called the "medial" and "lateral" compartments, respectively. The condyle is the smooth, rounded end of the femur that allows the femur to move easily over the surface of the menisci on the tibial plateau. The ligaments and tendons control the motion of the knee joint. The tendons connect the patella; the ACL (anterior cruciate ligament) and PCL (posterior cruciate ligament) prevent the tibia from sliding forward or backward and limit the tibia's rotation; the collateral ligaments minimize side-to-side motion and stabilize the knee.

Because the knee joint sustains the mechanical forces repeatedly throughout one's standing activities, and is one of the most mobile and flexible joints in the body, it is vulnerable to injury and degeneration. The knee is kept in alignment by the tendons and ligaments. Malalignment of the knee joint can occur when any of the tendons or ligaments is damaged. In particular, malalignment occurs when the tibia is translated and rotated relative to the femur. Malalignment of the tibia causes abnormal loading of forces across the knee and osteoarthritis (OA) of the knee. Knee OA is one of the most common orthopaedic problems with about six percent of US adults over 30 years of age suffering from this disease. The total cost of knee OA was estimated as $15.5 billion in 1994. Advanced OA often requires surgery to restore leg alignment, physical function, and reduce knee joint pain.

Though the malalignment of the knee is typically seen in valgus (bow-legged) or varus (knocked kneed) deformity, it also involves the rotational malalignment and translation of the tibia. In particular, the rotational and translational malalignment are often observed in the initial stage of knee OA when the valgus or varus deformity is not yet developed, and there is no treatment theory or methodology for correcting these components. Therefore, there is a need for developing a methodology for correcting the rotational malalignment to prevent further deformity.

Treatment for knee injury often involves therapeutic exercise programs with bracing, medication, and/or other physical therapy modalities. However, the current treatment regimens for knee exercise and therapy only focus on gaining muscle strength and restoring the range of motion. The equipment associated with that treatment does not correct the underlying knee malalignment. Thus, there is need in the art for exercise and treatment equipment that can correct knee malalignment while simultaneously strengthening and restoring the knee's range of motion.

SUMMARY OF THE INVENTION

The present invention helps patients restore the rotational alignment of the malaligned knee to that of a healthy knee, and restore the knee function by regaining the range of motion and strengthening of the knee muscles. Therefore, it can ultimately correct the deformity to the extent allowed by the underlying articular cartilage structural damage. Accordingly, the present invention provides a method of treatment for knee osteoarthritis by simultaneously correcting the knee rotational malalignment and restoring the knee function, which allows for an optimal loading distribution across the knee joint and ultimately minimizes cartilage degeneration.

The present invention is training and treatment equipment comprising a "rotation corrector". The rotation corrector is a novel assembly of leg holding device, which can rotate the knee passively without any leg muscle activity (where the patient positions the knee's rotation), actively (with some muscle activity of the leg against slight resistance) or resistively (with significantly all of the leg muscle activity overcoming the resistance to rotation). The rotational control of "the rotation corrector" is designed so that the tibia experiences an internal rotational torque as well as restrictive forces for a regulation of both AMRI and PLRI.

When the rotation corrector is mounted on the specially designed training equipment with the weight stack system to provide sufficient resistance, it can (1) allow the knee to regain normal rotational range of motion and correct the rotational malalignment of the knee, (2) allow the knee to regain the muscle function of rotational control, (3) restore the range of motion and muscle strength of the knee, and (4) correct the 3 dimensional knee malalignment. Additionally, the "reversible load transmission system" provides both leg extension exercise (for the quadriceps muscles) and leg curl exercise (for the hamstring muscles) in one apparatus. The machine can be utilized by the younger population, including athletes as well as others, to correct rotational malalignment and can be used in physical therapy clinics, athletic training facilities as well as fitness centers.

The rotation corrector mounted on specially designed treatment equipment can correct rotational malalignment. With a resistance provided by a rubber tube, it gives a sufficient resistance for strengthening the quadriceps muscles without the need for any other load generating means, including, for example, a weight stack. This treatment equipment can be used in physical therapy clinics or in the patients' home for their personal use.

BRIEF DESCRIPTION OF THE FIGURES

FIG 1: Rotation corrector

Fig. 1A and 1B illustrate the rotation corrector assembly for the training equipment and for the treatment equipment, respectively. Fig. 1C shows a horizontal dissection of the rotation corrector, and Fig. 1D illustrates how the rotation corrector rotates the tibia and regulates postero-lateral rotatory instability (PLRI) and antero-medial rotatory instability (AMRI). E, F, G, H and I show a proposed cuff that surrounds the tibia, and how it can be secured and attached to a sheet, thereby imparting a rotational force on the tibia.

FIG. 2: Training equipment

The training equipment can utilize a weight stack system for load adjustment and the rotation corrector to control tibial rotation as well as applying resistance to the lower leg. The seat, platform and footrest are designed for good accessibility of the patient and for stabilization of the patient's body during exercise.

FIG. 3: The seat

The seat is designed for proper positioning of the patient, good accessibility, and ease of use in aligning the knee onto the machine. The sliding thigh support provides better accessibility when it is in the slide-in position (Fig. 3A), and an appropriate thigh support when it is in the slide-out position (Fig. 3B). The height of the sliding thigh rest provides a tilt of the thigh, allowing increased flexion angle of the knee at its resting position under gravity.

FIG. 4: The platform and the footrest

The platform is the horizontal flat plate, allowing safe steps during the patient's access to an appropriate position in the seat.

The footrest is the tilted board on the platform, providing a secure positioning of the non-exercising leg's foot, and the counter force from the footrest allows the patient's body to be secured in a comfortable and stabilized position.

FIG. 5: The range limiter

The range limiter assembly can be a part of the rotation corrector, defining and controlling the maximum extension and flexion of the leg during exercise. (Fig. 5A). The range limiter disk is a part of the extension/flexion axis of the machine, and it rotates along with extension and flexion of the knee (Fig. 5B). A limiter bar connected to the side pole is projected into the circular track on the flat surface of the plate, which provides the space in which the limiter bar is allowed to travel (Fig. 5C). The range of motion is adjusted by location of the range limiter pins on the circular surface of the range limiter disk. The range limiter disk also contains a passage through which a vertical bar is located. This vertical bar is operably connected at one end to a rotational drum. This passage does not intersect or interfere with the circular track.

FIG. 6: Load transmission system

The load from a weight stack system can be transmitted through the belt to the load transmission disk. The belt can have a hook at its end, and the disk can have handles to connect to the belt's hook.

The hook is connected to a handle located posteriorly to the axis of the disk for knee extension ("leg extension") exercise (Fig. 6A), so that the load is applied on the rotational component as a resistance against the quadriceps muscles. For the knee flexion ("leg curl") exercise (Fig. 6B), the rotational component is initially brought up to the fully extended position, then the hook is connected to a handle located anteriorly to the axis of the disk.

FIG. 7: The treatment equipment

Fig. 7A is an overview of the treatment equipment using the rotation corrector assembly. The equipment is designed compactly and lightly to be used on a bed or a treatment table in clinics or patients' homes (Fig. 7B).

In terms of functionality, it has the same functions with the training equipment except the weight stack system as a load transmission is not included.

FIG. 8: Load application for the treatment equipment

Fig. 8A shows that the equipment has handles behind the rotational component, allowing a connection with a specially designed rubber band (Fig. 8C) for load transmission (Fig. 8B).

FIG. 9: Evaluation device for isokinetic strength testing machine

The rotation corrector can be attached to an isokinetic strength testing machine such as Biodex System 3, which allows a knee strength evaluation in a given rotational alignment.

Fig. 9A shows an overview of the isokinetic testing machine with the rotation corrector attached. Fig. 9B shows the support pole. Fig. 9C shows the rotation corrector attached to the isokinetic testing machine and the support pole viewed from the front of the machine.

DETAILED DESCRIPTION OF THE INVENTION

The embodiments of the present invention are used to treat a variety of knee problems, which involve the rotational malalignment of the knee joint, mainly focusing on the osteoarthritis. "Rotational alignment" is used to describe the amount the tibia is rotated compared to the femur. Rotational alignment can be measured by extending the leg and measuring the angle the foot makes, in a locked position, with the femur. When the foot and knee line up, the knee is rotationally aligned. When the tibia is rotated such that the foot rotates in an outward direction from the body's center, the knee (or tibia) is "externally rotated." If the tibia rotates in the other direction, toward the inside of the body, the knee is "internally rotated." When the rotation angle is regarded to be excessive for maintaining the normal knee function and structure, it is stated as "rotational malalignment."

Rotational malalignment is multi-factorial. Components of rotational malalignment are a combination of translation and rotation of the tibia, relative to the femur. The ligaments normally restrict tibial translation, but if any are damaged the tibia may move, relative to the femur, forward (anterior), backward (posterior), inside (medial) and outside (lateral). The rotational malalignment causes an abnormal loading pattern, which can accelerate degeneration of the articular cartilage in the knee joint. Therefore, the present invention simultaneously corrects the tibia's rotational malalignment and translation to reduce and correct abnormal loading across the joint.

A precise observation reveals that the tibia is both externally rotated and laterally translated in the varus (bowlegged) knee. This positioning of the tibia causes an abnormal pressure distribution over the tibia. In particular, the unbalanced pressure in the varus knee causes excessive compression of the medial compartment of the knee even in the non-weightbearing position. The maximum pressure on the medial compartment occurs with standing and the condition progressively worsens under continued rotational malalignment during gait. The present invention prevents this worsening by simultaneously correcting tibial translation and abnormal rotational alignment. This correction occurs by restoring the external rotation contracture (meaning loss of normal internal rotation), followed by restoring the knee range of motion and by strengthening the muscles under the corrected rotational alignment. Repeated use of this invention can help patients restore normal knee function, and the worsening process of knee OA can be delayed more effectively with an application of the knee brace outlined in the previously filed provisional patent application (attached as an appendix and incorporated in the present application) than with the use of the leg exercise equipment alone.

As used herein, "operably connected" means two or more parts are connected such that the movement of one part affects the operation of the other part.

A "rotation corrector" refers to the piece of the exercise equipment that generates and imparts to the leg a rotational force on the tibia that acts to correct for the tibia's rotational malalignment. The term includes, as shown in the examples, any means to surround and secure the tibia and means to impart a rotational force to the tibia. The force can be generated by any means known in the art, including by the user rotating the device. The leg can be secured by any means known in the art including a cuff to surround the leg. The cuff can be flexible and cushioned to provide comfort for the user's leg. Alternatively, the cuff can be more rigid, made of plastic or metal to more securely hold the user's leg in place. The cuff can also comprise a combination of rigidity and cushioning to maximize the ability to hold the leg in place while also increasing the surface area in contact with the leg to avoid pain by leg compression. For instance, the cuff can contain a metal plate surrounded by soft material such as polyurethane foam and covered by artificial leather for coating.

Means to secure said cuff around said leg include, for instance, belts and hooks with adjustable positions to secure the cuff around various-sized legs. Velcro may also be used. The cuff need not be in one piece. A cuff comprised of multiple pieces to surround the leg provides a means to control the location of the force generated on the tibia.

A "rotational drum" is one means whereby a rotational force can be imparted onto the tibia. The particular circumferential shape of the drum is not important so long as the rotation of the drum results in movement of a sheet attached to the drum to which the cuff is also attached.

The "sheet" is any material that is non-elastic and can withstand multiple exercise repetitions without failure. To prevent slippage, the sheet is attached to the rotational drum by any means known in the art, including by permanent means such as screws. The sheet is also attached to the cuff by any means known in the art including permanent means such as sewing or stapling and temporary means, including fasteners, to permit the cuff or sheet to be independently changed or cleaned.

"Range limiter disk" is a device to restrict the range of motion of the leg as the user flexes and extends the leg. The range limiter disk comprises a "curved track" through which an immovable range limiter is placed. The track traveling over the bar defines the range of leg motion. As the disk rotates with flexion and extension of the knee during exercise, the range limiter bar, which is immovable during leg exercise, contacts each end of the track, thereby

restricting the amount the knee joint can flex or extend. This range can be controlled by any means that can vary the limit of the track. For example, two pins with various holes along the track's location, can be utilized to control the range of motion.

The rotation corrector can also include a "resistance adjustment pin" and an associated resistance means to control the amount of force the knee must overcome to rotate. The resistance means can include overcoming an elastic. It can also utilize a brake such as a rubber pad in contact with an element which moves against the rubber pad when the rotation corrector is operated against metal whereby increasing brake friction increases the force the knee rotation must overcome. Means to lock the leg into position after the knee has been properly positioned can be included.

A "load generating" device can be any means whereby a force is generated that the leg must overcome during flexion or extension. Such means include weight stacks or viscous-generated forces whereby force is always applied in the direction of motion, irrespective of the direction of motion during rotation.

"Extension/flexion axis of the machine" refers to the motion of the leg during exercise as the leg travels from a flexed position, to an extended position, and back to the flexed position.

The examples provided herein are for illustrative purposes only, and are not intended to limit the scope of the invention as claimed herein. The appendix also forms part of this application.

Figure 1 illustrates "the rotation corrector", a component specially designed to rotate the tibia passively, actively or resistively at a given angle of knee flexion or during knee extension/flexion exercises. The passive knee rotation, meaning the tibia is rotated by an external force, namely by a force generated by the patient's arms, is utilized to correct the external rotation contracture, or to increase the range of motion of the knee toward the internal rotation. This force can be generated by manipulating the vertical bar by, for example, a rotation handle <2> at the top-outside of the component by the patient. For active rotation, the patient can voluntarily rotate the tibia inwardly by activating the internal rotator muscles of the knee joint against no resistance and this exercise would be used to reeducate the muscles to change the rotational alignment toward normal state. The resistive rotation is the muscle strengthening exercise for the internal rotators of the knee. The resistance adjustment pins <1> at the top of the rotation corrector allow an adjustment of rotational resistance of the rotational drum <5> located at each side of the tibia from freely rotating to locked in a fixed position. When the drum is locked

in position there is no movement of the rotational drum and can be used to maintain the rotational position. The zero resistance provides a free-to-rotate environment for the tibia, allowing active rotation exercise or passive rotation control for the patient. Any resistance level between freely rotating and locked in position provides a resistive training environment.

Figure 1A shows the rotation corrector for a piece of training equipment and Figure 1B shows the rotation corrector for a piece of treatment equipment that is described below in detail. In addition, these rotation correctors can be used as a part of a device or machine for other purposes such as isokinetic knee strength testing by acting as an interface to connect with an isokinetic testing machine available. Furthermore, this assembly can be used for precise in-vivo measurement of the rotation angle of the tibia during knee extension or flexion exercise.

Element <1> is the resistance adjustment pin to regulate the resistance of the rotational drum <5> from zero to infinite. Element <2> is the rotation handle, which allow the patient to rotate his/her tibia passively. Element <3> is the range limiter disk, which rotates along with knee extension or flexion, and an engagement of the track in the range limiter disk and an immovable range limiter bar projected from the side pole, as seen in Fig. 5(c), define the maximum range of motion of this apparatus. Elements <4> are the range limiter pins, which can reduce the range of motion by physically interrupting the path of the range limiter bar. Elements <5> are the rotational drums, which rotate along with the rotational handle <2>. Simultaneous rotation of both drums create a tibial rotation. Elements <6> (Fig. 1A) and <8> (Fig. 1B) are connection bars, which provide a rigid connection between the rotational drums (in Fig. 1A) and the range limiter disk (in Fig. 1B) in extension and flexion, while the rotational drums remain free-to-rotate. Element <7> is a non-elastic sheet which transmits the torque of the rotational drums into a tensile force of the sheet itself, which also contains shin pads and a calf pad (shown in Figs E – I) to hold the tibia securely and rotate the tibia.

Figures 1C and 1D are horizontal dissections of the rotational drums and illustrate that a simultaneous rotation of the two rotational drums enables not only protestation of the tibia but also reduction of excessive tibial displacements associated with AMRI or PLRI. This system allows the patient to find an optimal rotational position of the tibia while executing strength training for the quadriceps or hamstrings.

Figure 1E and 1F shows the details of the rotation corrector horizontally and frontally, respectively. The calf pad <8> and the sheet <7> are firmly attached posteriorly. The shin pads are composed of two parts, right shin pad <9> and left shin pad <10>. The left shin pad <10> can be one large pad to give a pressure on the left front side of the shin, which is covered by a non-

elastic sheet. The right shin pad <9> can be composed of multiple (preferably 3 or 4) small pads (Figure 1G), which permit adjustment of tightness as well as circumferential adjustment to accommodate different lower leg sizes. Belts <11> can be attached to the front part of the calf pad <8> and travel on the outside of the right pads <9> (see Figs. 1G and 1H), which give a compression force toward the right front side of the shin. In the front, the right pad can be attached to the sheet as shown in Figure 1H, and holes can be made in the elastic sheet <7> for the belts to travel through, therefore pulling the belts causes no motions on the right shin pad and the sheet but a compression force on it. The front part of the left shin pad <10> is attached to one edge of the Y shaped sheet (see Fig. 1I), and the front edge of the right shin pad <9> (see Fig. 1H) slides into the right wedge of this Y sheet. The free end of the Y sheet contains holes <12> for the belts to travel through and rings <13> (shown in Fig. 1I) to fold the belts <11> (shown in Fig. 1H). Between the sheets and belts are Velcro surfaces to stabilize the system to provide sufficient compression on the shin.

Figure 2 illustrates an overview of the training equipment with the rotation corrector <A> assembly (originally shown in Fig. 1). <B> is a specially designed seat for ease of use, more fully described below. Because of the structure of the rotation corrector, the patient needs access to the required position between the seat and the rotation corrector. Element <C> is the platform and footrest assembly. The sliding thigh rest <F> is designed on the front of the seat. A weight stack system <D> can be utilized for resistance, and the load from the weight stack system can be transmitted through the belt <G> to a reversible load transmission disk <E>, to allow both a knee extension exercise and a knee flexion exercise on one apparatus (as discussed below and shown in Fig. 6).

Figure 3 illustrates the structure of the seat. The back support <1> tilts from the horizontal line, preferably 50 degrees, to allow a comfortable seated positioning for the patient. The hip rest <2> is flat and horizontally aligned, and is wide enough to allow appropriate positioning for the exercises of both right and left knees. The sliding thigh rest <3> is used to stabilize the thigh of the leg being trained at its slide-out position (3B), whereas it slides in for better patient access to the training position (3A). Figure 3C illustrates the height of the sliding thigh rest, which can make a 20 degree tilt so that knee reaches 110 degrees at its resting position (tibia being vertical) under the effect of gravity.

Figure 4 illustrates the structure of the platform <1> and the footrest <2> assembly. The platform is the horizontal flat plate, allowing safe steps during the patient's access to an appropriate position in the seat. The footrest is the tilted board on the platform, providing a secure

positioning of the foot of the leg not being exercised, and the counter force from the footrest allows the patient's body to be secured in a comfortable and stabilized position.

Figure 5A shows detail of the range limiter assembly. Element <1> is the range limiter disk, which rotates along with knee extension or flexion because of the vertical bar <7>. Because there is a passage through which the vertical bar travels (indicated by the dashed lines in Figs. 5A and 5C), the range limiter disk does not move with rotation of the tibia. Element <3> is the immovable range limiter bar, which can be attached to a side pole <10> and has no fixed attachment to the range limiter disk. In one embodiment, the range limiter bar <3> travels through the range limiter disk via a track <4> through the range limiter disk and so defines the maximum range of motion. Because the maximum range of motion for leg exercise is, at most, approximately 120 degrees, the passage through which the vertical bar can pass can be made in a range limiter disk that has a track made through the thickness of the range limiter disk. Element <2> is the range limiter pin, which allows the patient to limit the range of motion by interrupting the excursion of the range limiter bar during the knee exercises. Alternatively, there can be a track in the range limiter disk, which does not extend all the way through the thickness of the disk, along which the immovable range limiter bar travels.

Figure 5B shows an interaction of the range limiter assembly and the rotator drum <8> with associated parts. The rotation handle <5> and the vertical bar <7> are rigidly connected to each other. The connection bar <9> provides stability between the rotator drums <8> to ensure they remain parallel to each other, while allowing free rotation of the rotator drum around the vertical bar. The vertical bar <7> travels through a passage in the range limiter disk vertically, and rotational movement of the vertical bar is maintained. The range limiter disk <1> is a part of the extension/flexion axis of the machine, and it moves with flexion and extension of the knee.

Figure 5C shows an interaction of the range limiter disk <1> and the side pole <10> along with the range limiter bar <3>. An engagement of the range limiter disk's track and a range limiter bar projected from the side pole define the maximum range of motion of this apparatus. Since the range limiter disk is a part of the rotation corrector, this system allows adjustments of the range of the knee motion during exercises using the range limiter pins <2>. Element <11> is, if present, connected to means for generating a load (not shown in Fig. 5) and is not connected to the side pole <10>.

Figure 6 shows the reversible load transmission system, which allows for changing the directions of the load for both knee extension and knee flexion exercises. The load from the

weight stack system is transmitted through the belt <1> to the load transmission disk <4>. The belt has a hook <2> at its end and the disk has multiple handles <3> to connect with the hook.

Figure 6A illustrates an interaction of the hook <2> on the belt <1> and the handle <3> on the load transmission disk <4> during the knee extension exercise. The hook <2> is connected to a handle <3> located posterior to the axis of the load transmission disk, so that a counter-clockwise load is applied on the rotation corrector as a resistance against a clockwise motion (large arrow).

Figure 6B illustrates an interaction of the belt's hook <2> and the disk's handle <3> during a knee flexion exercise (or the leg curl). In this case, the hook <2> is connected to the to a handle <3> located anterior to the axis of the disk when the knee is in the fully extended position. Therefore, the clockwise load is applied on the rotation corrector against counter-clockwise rotation during the knee flexion exercise.

Figure 7A shows a perspective view of the treatment equipment. The rotation corrector assembly is used as a core system along with other supporting structures. The equipment is designed compactly and lightly to be used on a treatment table in clinics or on furniture at patients' homes as shown in Figure 7B.

Element <1> is the base board, adapted to be placed on a treatment table (element <10> in Fig. 7B) and to provide stability of the rotation corrector on the treatment table along with the belt <2>. The base board has a soft-coated thigh support box, which provides a comfortable support for the patient's thigh as well as contains the connection bar (Figure 1B <8>).

In terms of structure and functionality, the treatment equipment has the same functions as the training equipment, though the resistance can be applied without the need for a load transmission system, for example by elastic means such as a rubber band for knee extension exercise. Element <3> is the resistance adjustment pin to regulate the resistance of the rotational drum <8> from zero to infinite. Element <4> is the rotation handle, which allow the patient to rotate his/hers tibia passively. Element <6> is the range limiter disk, which rotates along with knee extension or flexion, and an engagement of a track in the range limiter disk and a range limiter bar projected from the side pole define the maximum range of motion of this apparatus. Element <8> is the rotational drum, which rotates along with the rotational handle <4> and a simultaneous rotation of both drums creates a tibial rotation. The connection bar is hidden in the thigh support box <1*>, which provides a rigid connection of the both sides of the rotation corrector during extension and flexion exercise, while the rotational drums <8> remain free to

rotate. Element <9> is a non-elastic sheet which transmits the torque of the rotational drums into a tensile force of the sheet itself, which also contains shin pads and a calf pad to hold the tibia securely and rotate the tibia.

Figure 8 illustrates a load application system of the treatment equipment. The rotational drum has handles <1> on its hind surface, which provide connection with hooks <3> of a rubber band <2> (see Figs. 8B and 8C). The rubber band is designed as shown in Figure 8C, allowing gradual increase in the resistance as the rubber band extends during knee extension exercise. The elastic properties of the elastic band (e.g. Young's Modulus) can be manipulated by means known in the art.

If the hooks <3> are connected with the upper handles <1>, the force generated by the rubber band <2> provides so-called proximal resistance on the tibia, providing posterior shear force and preventing anterior shear of the tibia. This is extremely useful when treating patients with anterior instability of the knee.

Figure 9A illustrates the rotation corrector attached to an isokinetic strength testing machine, such as Biodex System 3, which allows a knee strength evaluation in a given rotational alignment. In a healthy knee, rotational alignment does not significantly affect the strength of the knee. In contrast, the joint pressure distribution associated with rotational malalignment can significantly affect the strength because an excessive pressure on the affected or damaged cartilage may disturb a normal kinematics of the knee joint. The result can provide the patient with information about the optimal rotational alignment as well as deteriorating positions for knee strength exercises.

Figure 9B shows the support pole, which provides a support for the far side of the rotation corrector. It allows a side to side sliding as well as a height adjustment. Figure 9C shows the rotation corrector attached to the isokinetic testing machine and the support pole viewed from the front of the machine.

I claim:

1. A leg exercising apparatus comprising a rotation corrector to exert a rotational force on a tibia to correct rotational malalignment in said tibia during leg exercise.

2. The leg exercising apparatus of claim 1 wherein said rotation corrector comprises:
    a. a cuff to surround the tibial portion of a leg and means for securing said cuff around said tibial portion of the leg;
    b. two rotational drums positioned on each side of said cuff;
    c. a sheet comprising means to attach said sheet to each of said rotational drums and also comprising means to attach said sheet to said cuff so that the rotation of said rotational drums imparts a rotational force to said tibial portion of the leg;
    d. a vertical bar operably connected at one end to one of said rotational drums and operably connected to means for rotating said vertical bar;
    e. a connector connecting each of said rotational drums so that said rotational drums remain parallel to each other.

3. The leg exercising apparatus of claim 2 wherein said cuff comprises:
    a. a calf pad and a shin pad.

4. The leg exercising apparatus of claim 3 wherein said rotation corrector further comprises:
    a. a range limiter disk having passage in which said vertical bar is disposed such that said disk rotates with extension and flexion of said leg during exercise;
    b. said range limiter disk being rigidly connected to a load transmission means;
    c. said range limiter disk further comprising a curved track;
    d. an immovable range limiter bar extending into said curved track such that said range limiter bar and said curved track limit rotation of said range limiter disk.

5. The leg exercising apparatus of claim 4 wherein said rotation corrector further comprises:
    a. a range limiter pin operably connected to said range limiter disk to control the range of motion of said range limiter bar during flexion and extension and means for varying the location of said range limiter pin on said hollow track.

6. The leg exercising apparatus of claim 5 wherein said rotation corrector further comprises:
    a. a resistance adjustment pin connected to said vertical bar;
    b. resistance means connected to said resistance adjustment pin and said rotational drum such that said resistance adjustment pin controls the force required to rotate said rotational drum.

7. The leg exercising apparatus of claim 6 wherein said rotation corrector further comprises:
   a. a handle attached to said vertical bar so that the user can rotate said rotational drum by rotating said handle.

8. The leg exercising apparatus of claim 7 further comprising:
   a. a load transmission disk rigidly connected to said range limiter disk;
   b. a belt connected at one end to said load transmission disk and at the other end operably connected to a load generating device.

9. The leg exercising apparatus of claim 8 wherein said equipment is a leg extension machine.

10. The leg exercising apparatus of claim 8 wherein said equipment is a leg curl machine.

11. The leg exercising apparatus of claim 8 further comprising a load transmission system comprising means for reversing the direction of resistance for both knee extension and knee flexion.

12. A method for correcting rotational malalignment of the knee comprising altering an abnormal rotation of the tibia by applying a rotational torque to the tibia during leg exercise.

Fig 1

Rotation Corrector

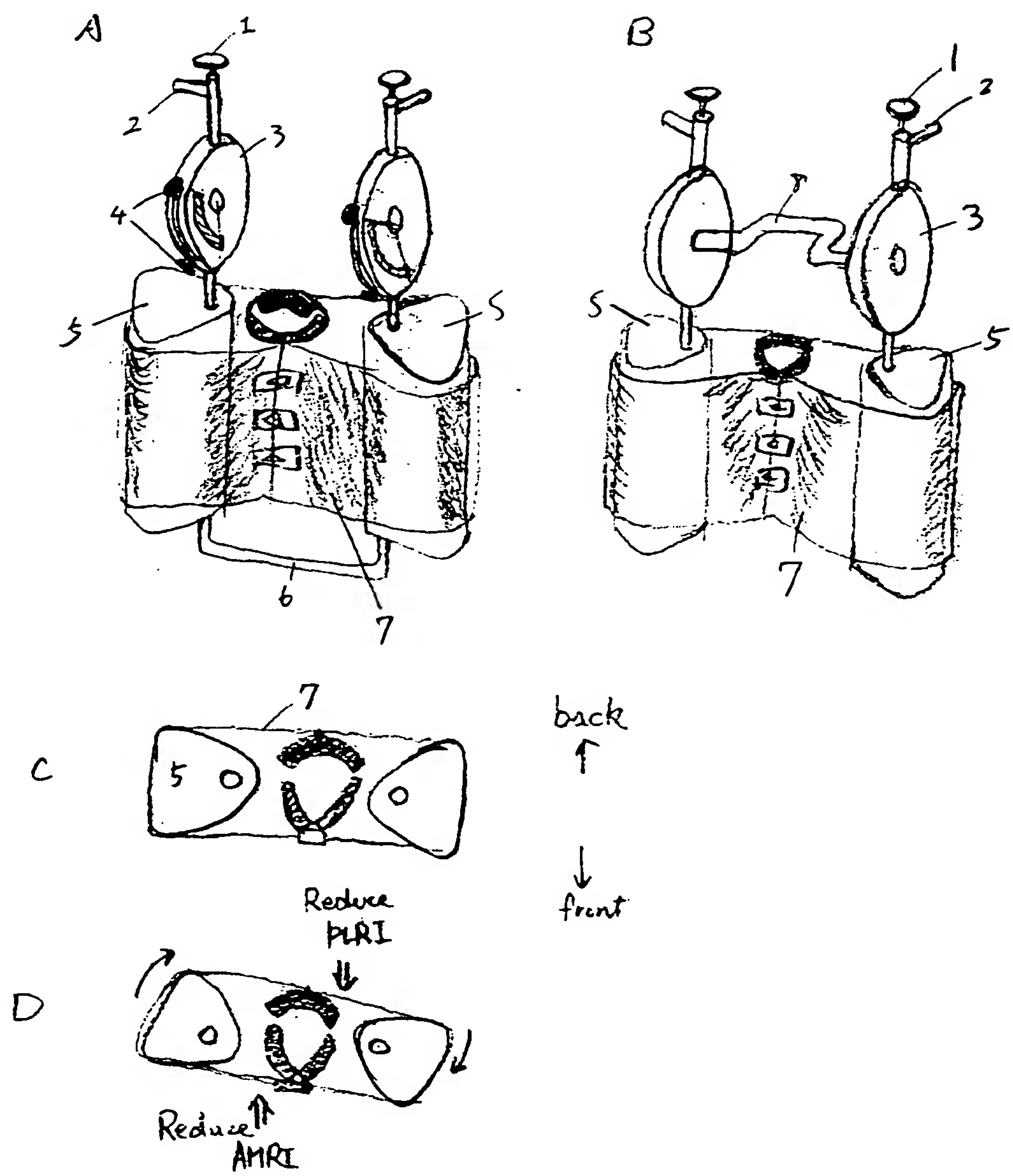

Fig 1

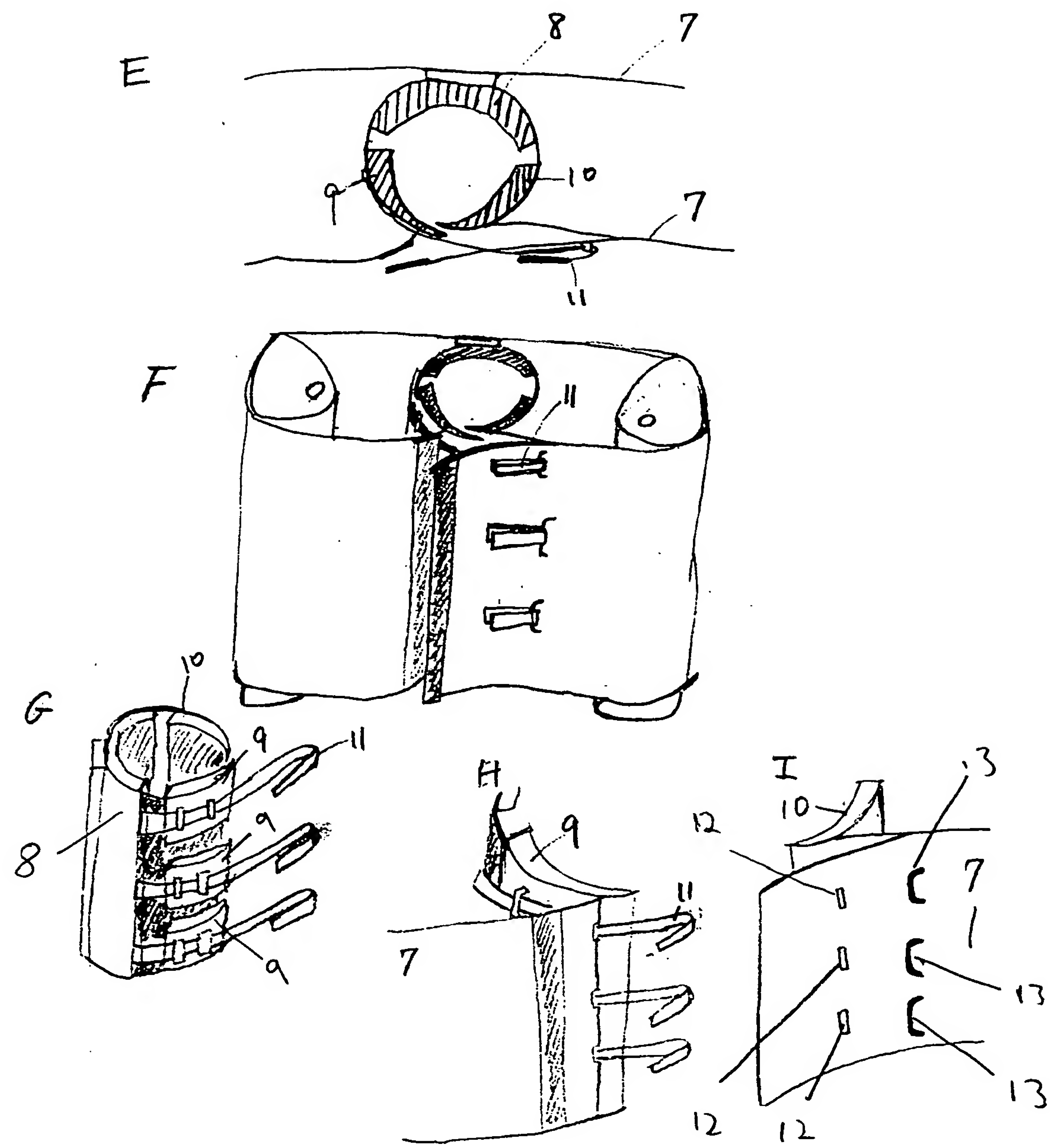

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Fig 2   Overview of Training Equipment

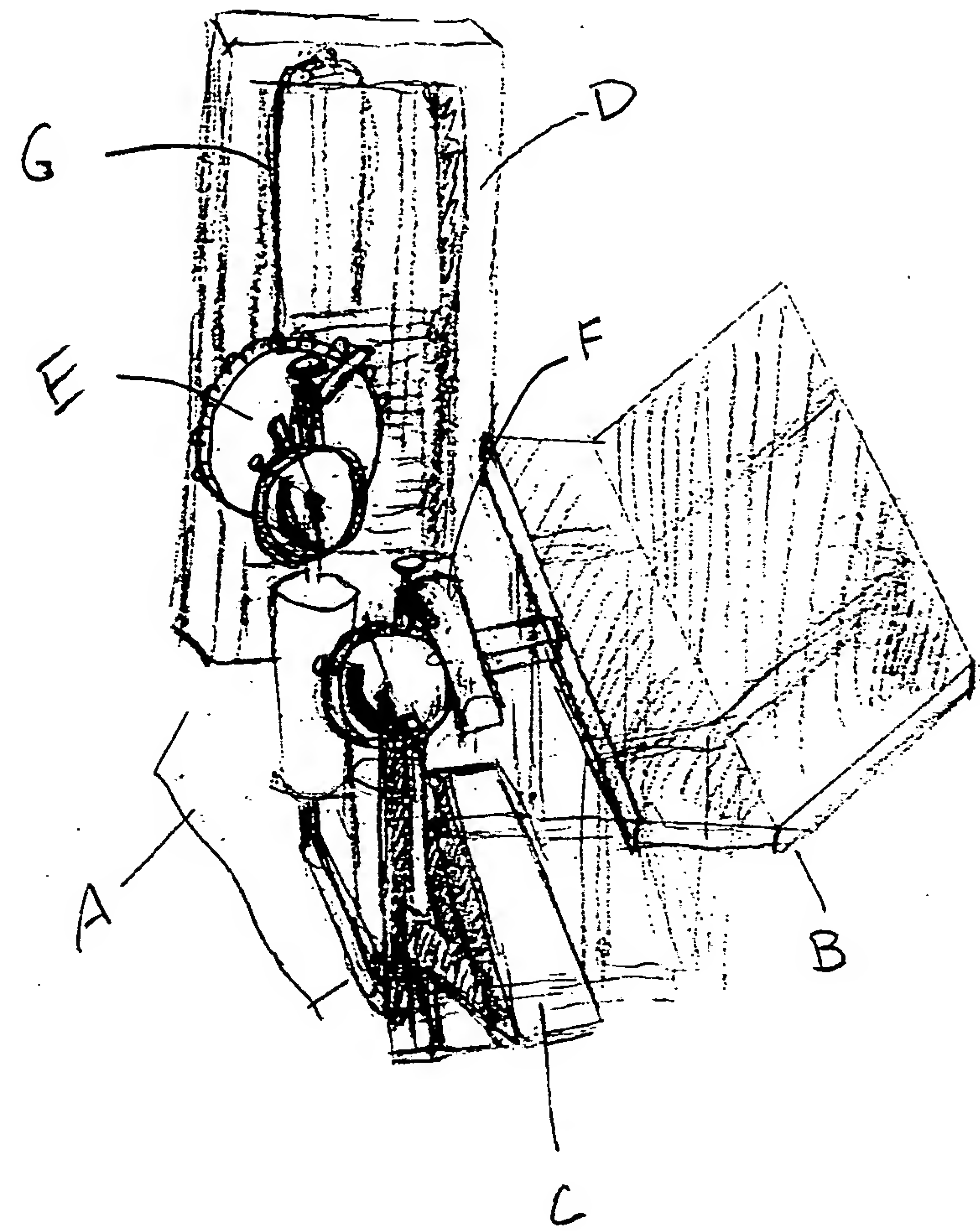

Fig 3 Seat

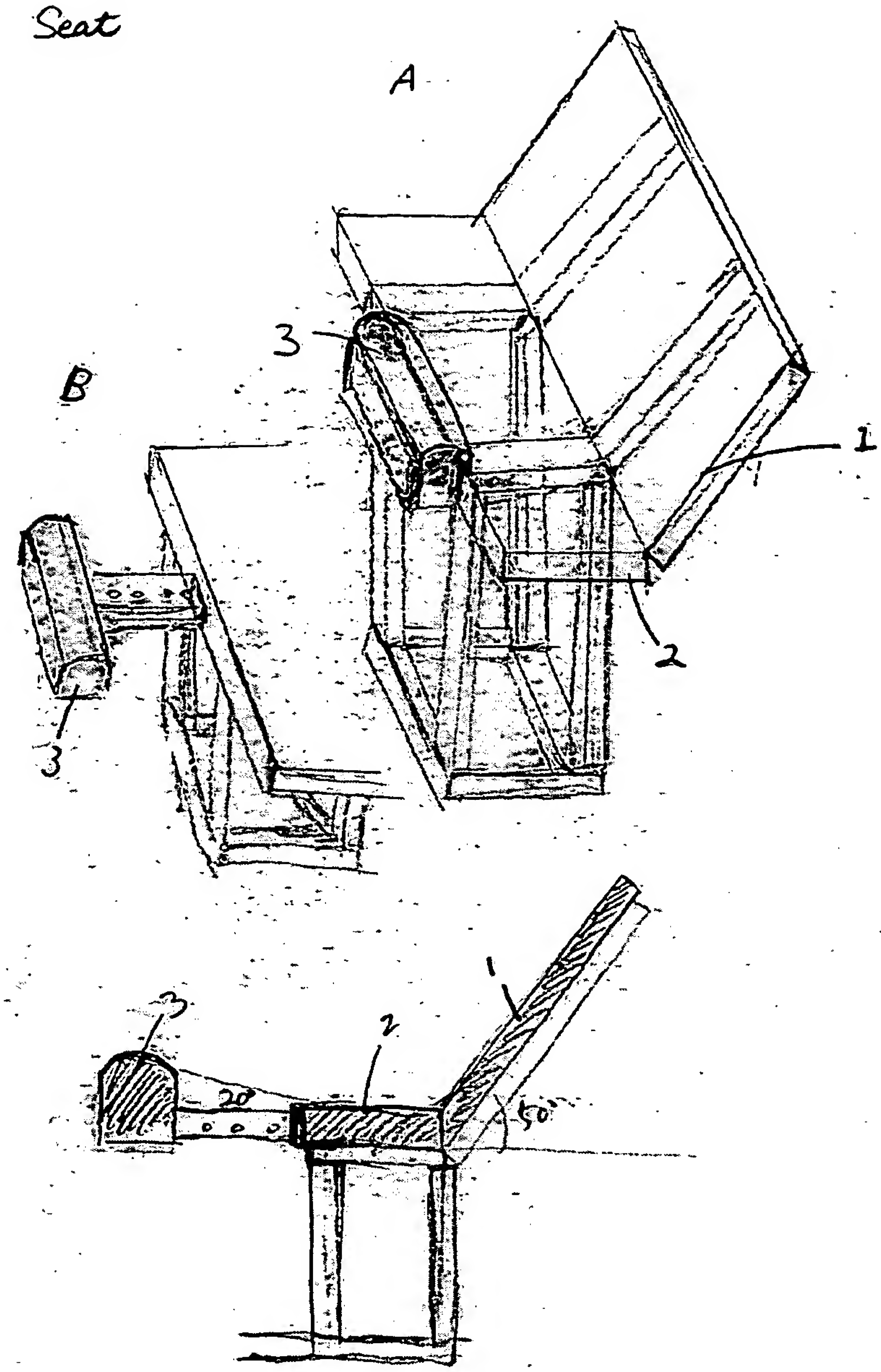

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Fig 4 Platform Footrest

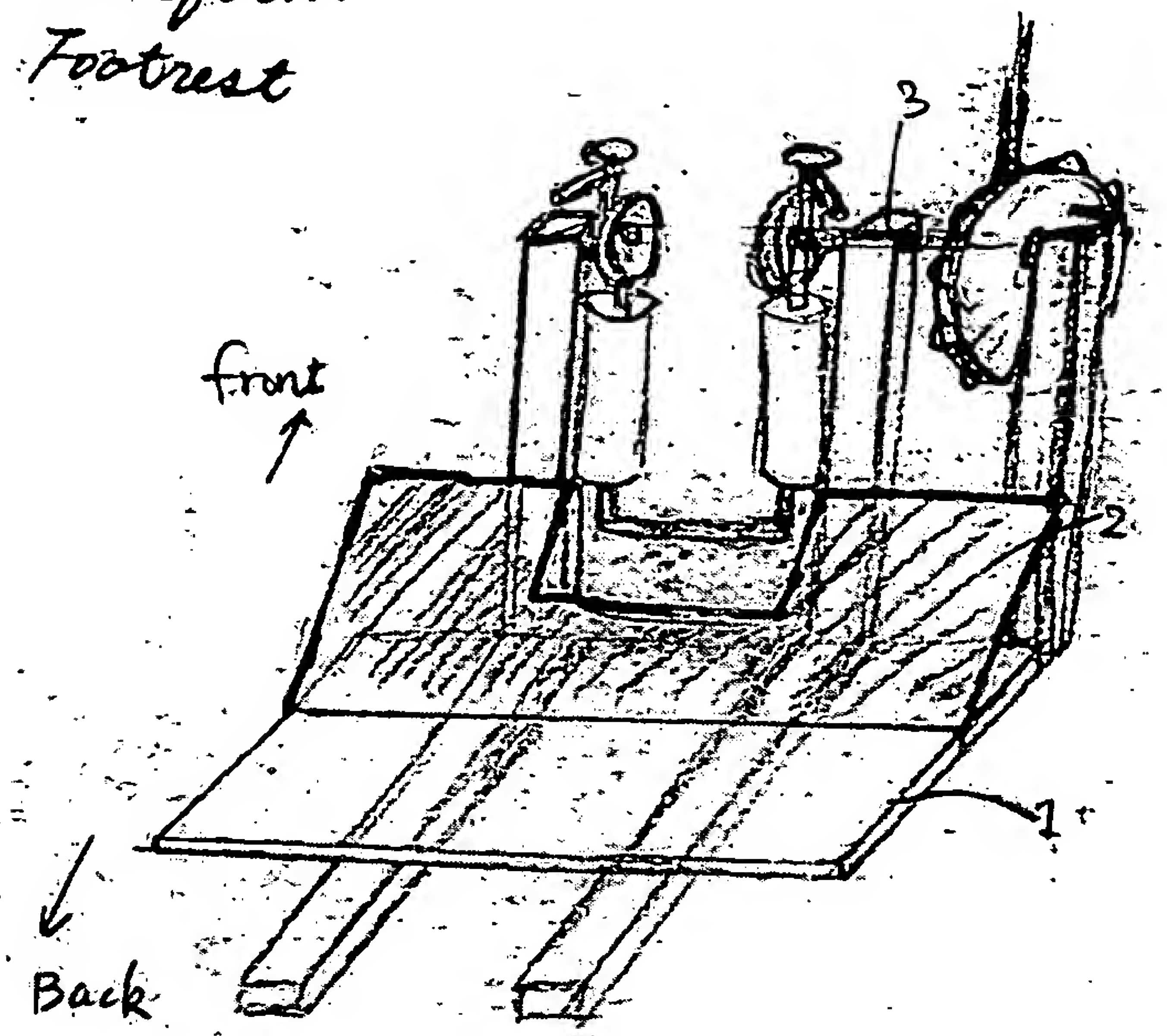
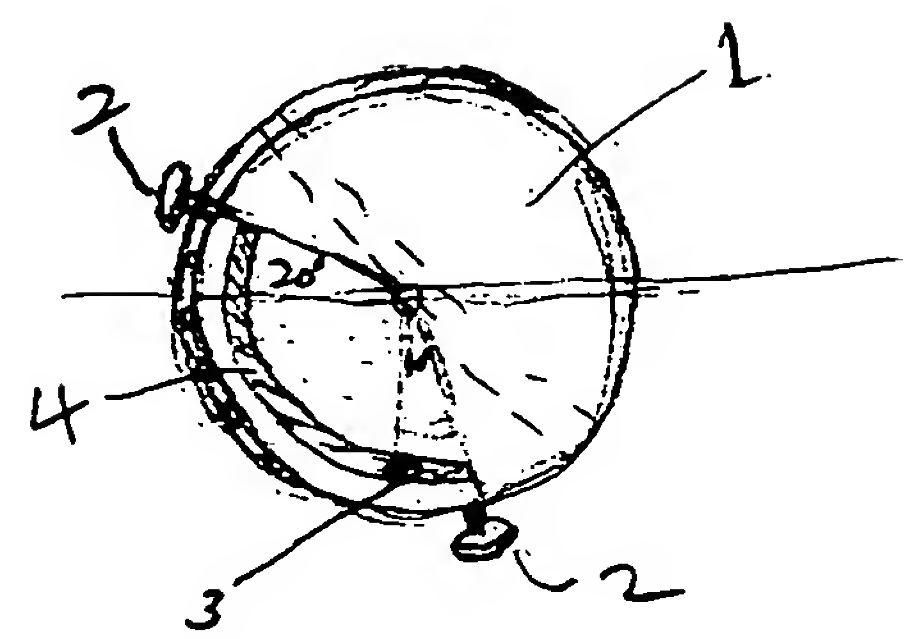


Fig 5

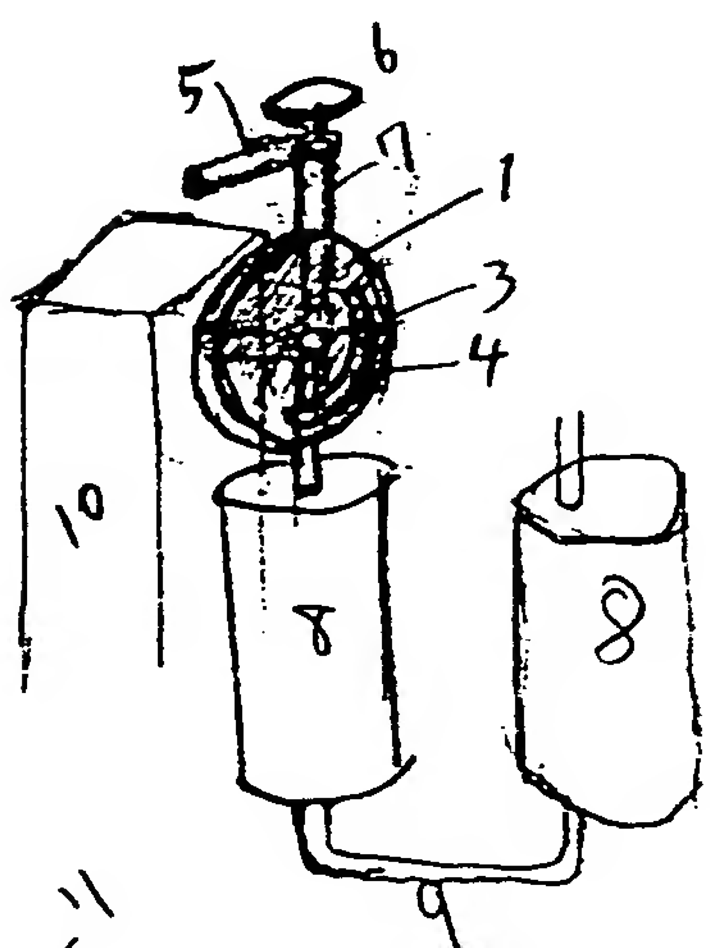
Range Limiter

A



B

Posterior view



C

Anterior view

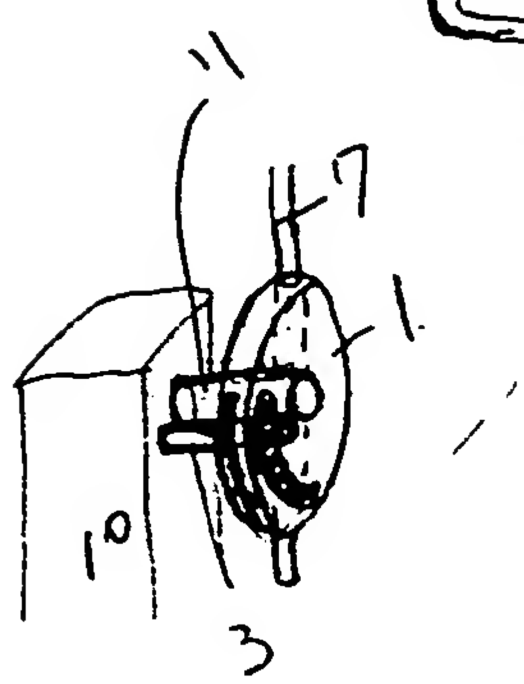
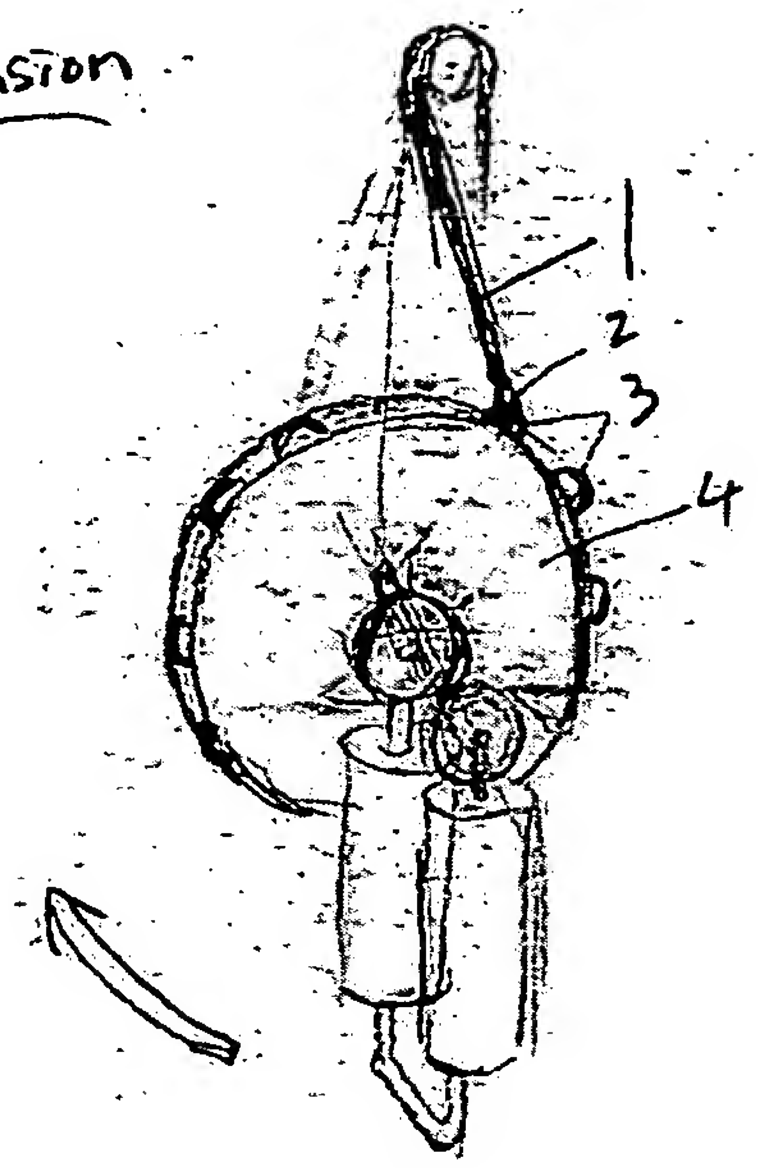


Fig 6

Load Transmission system

A. Knee extension



B. Knee Flexion

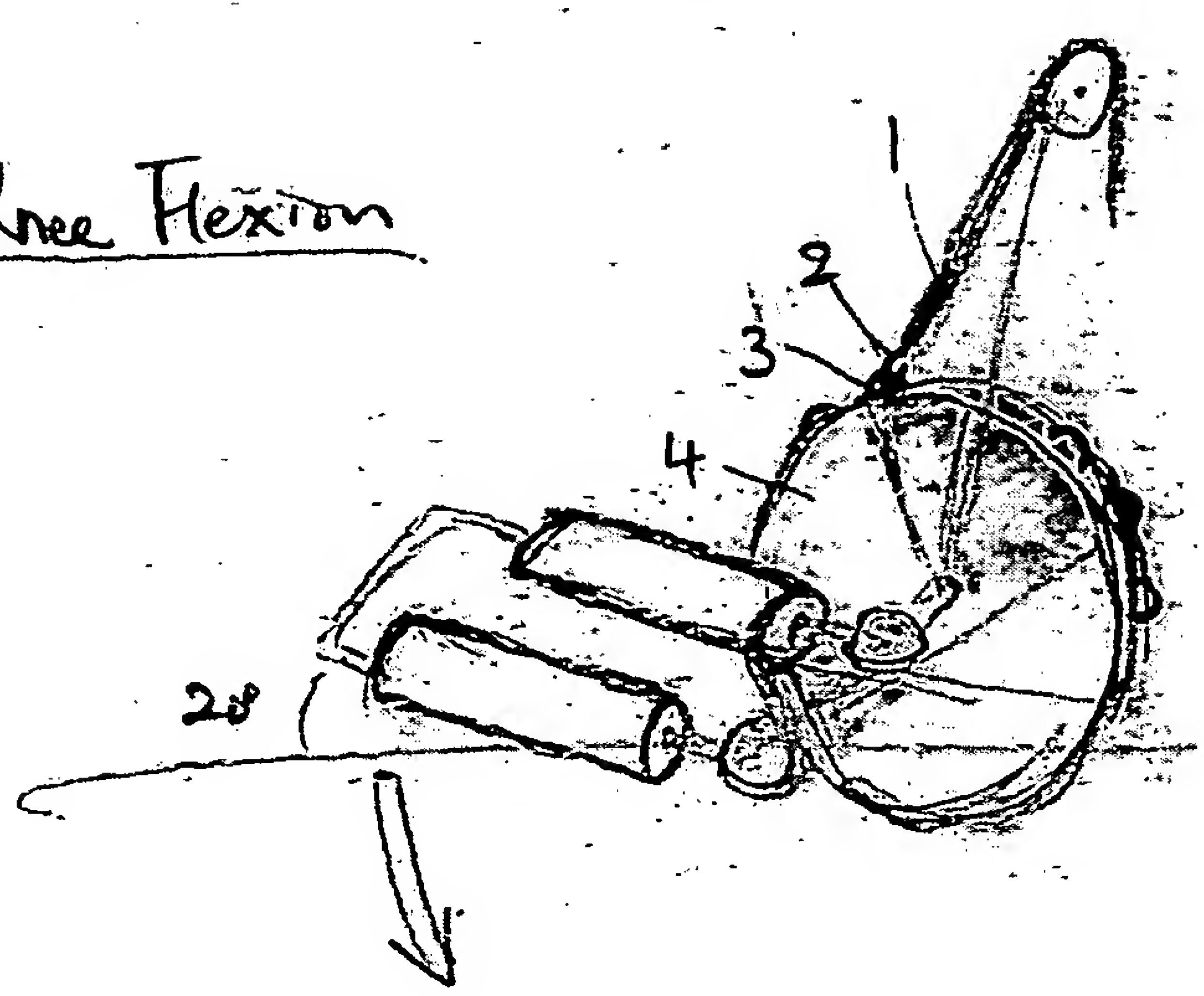


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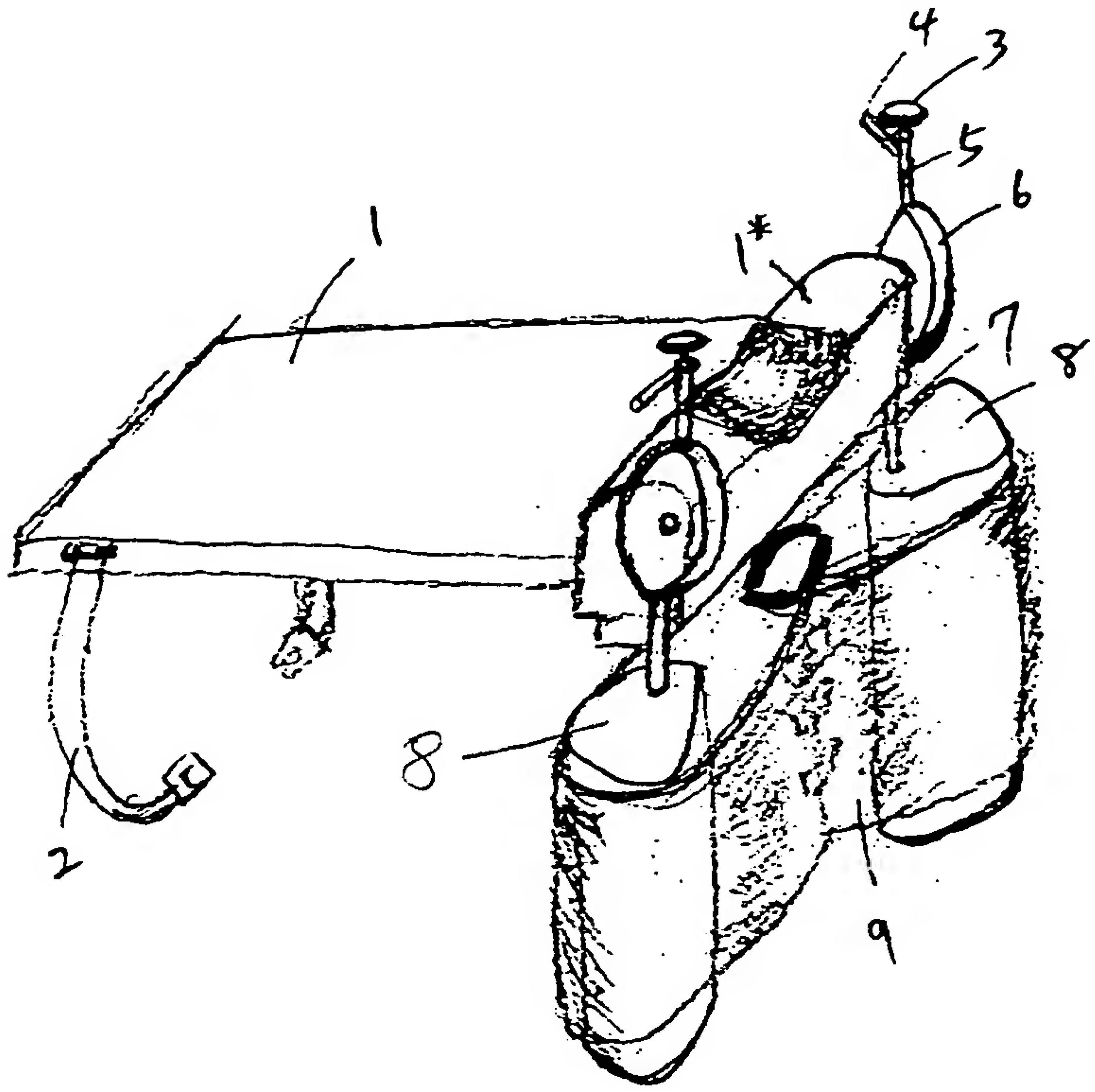
Fig 7

Overview of Treatment Equipment

A



B

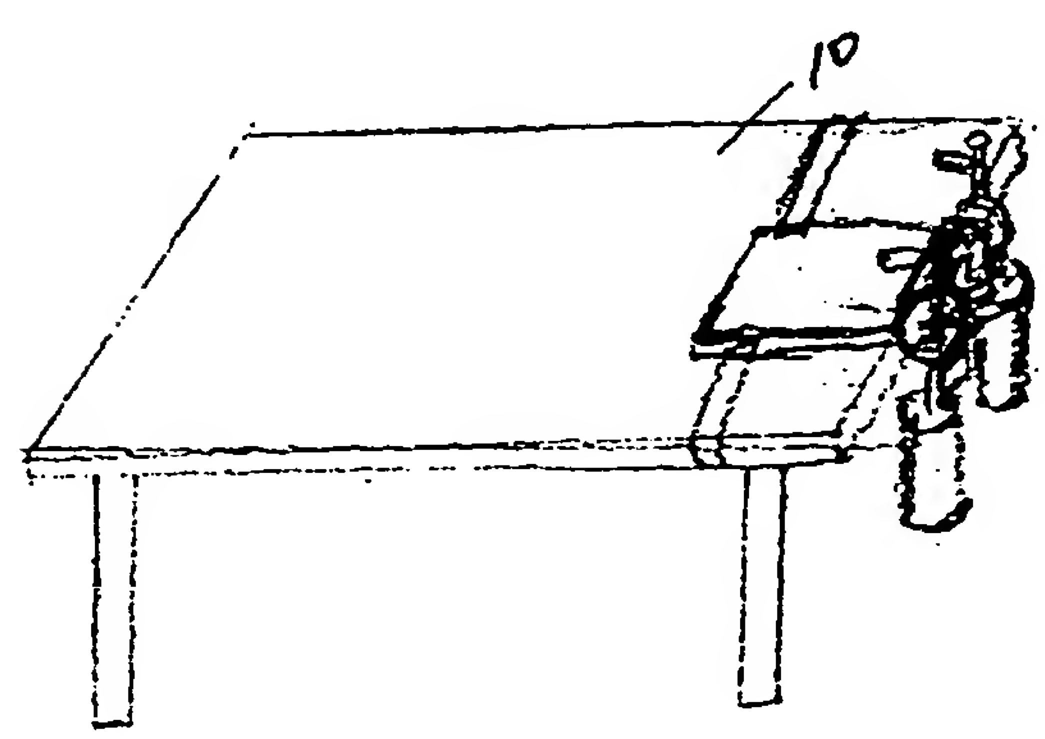


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Fig 8

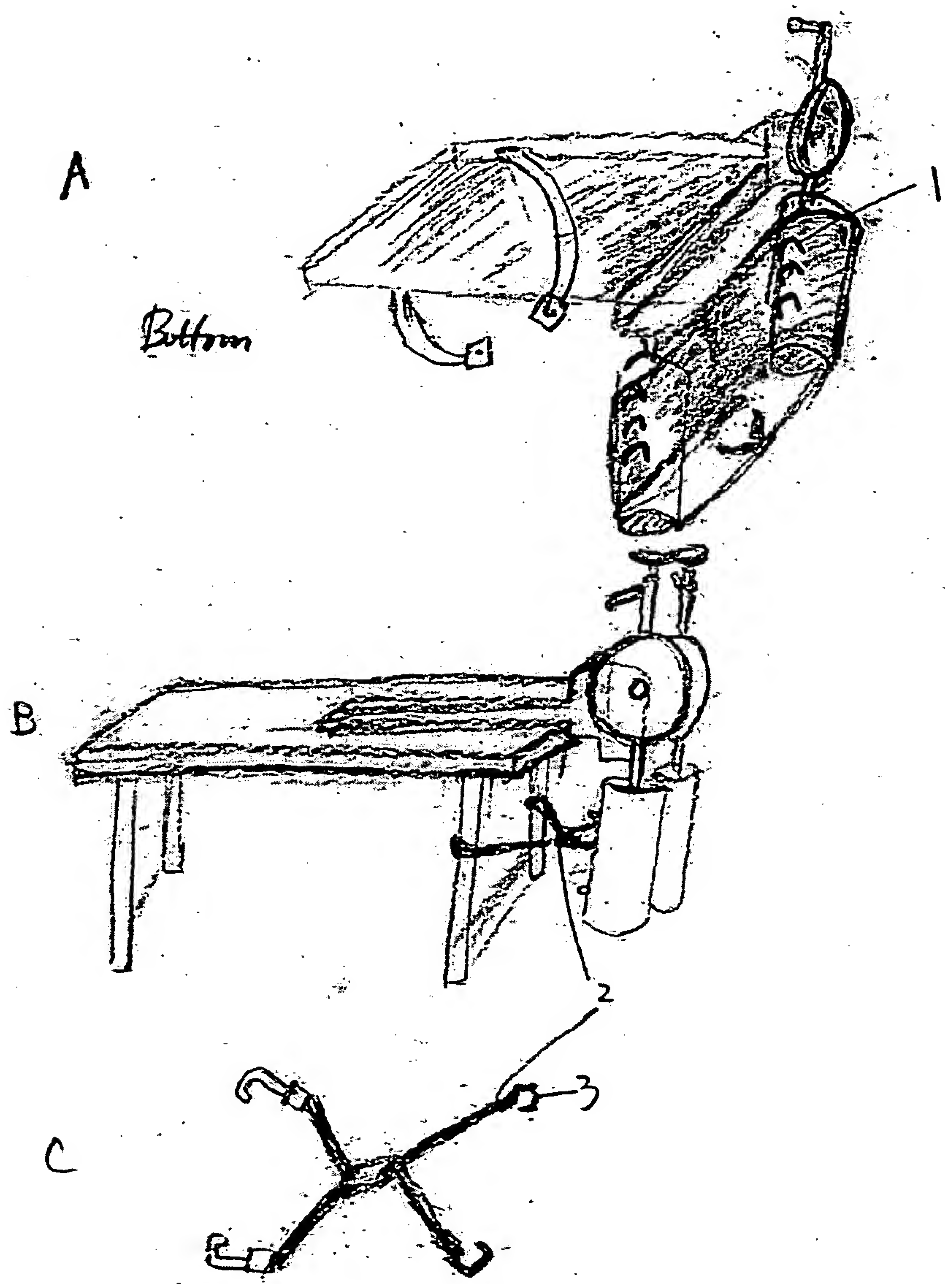

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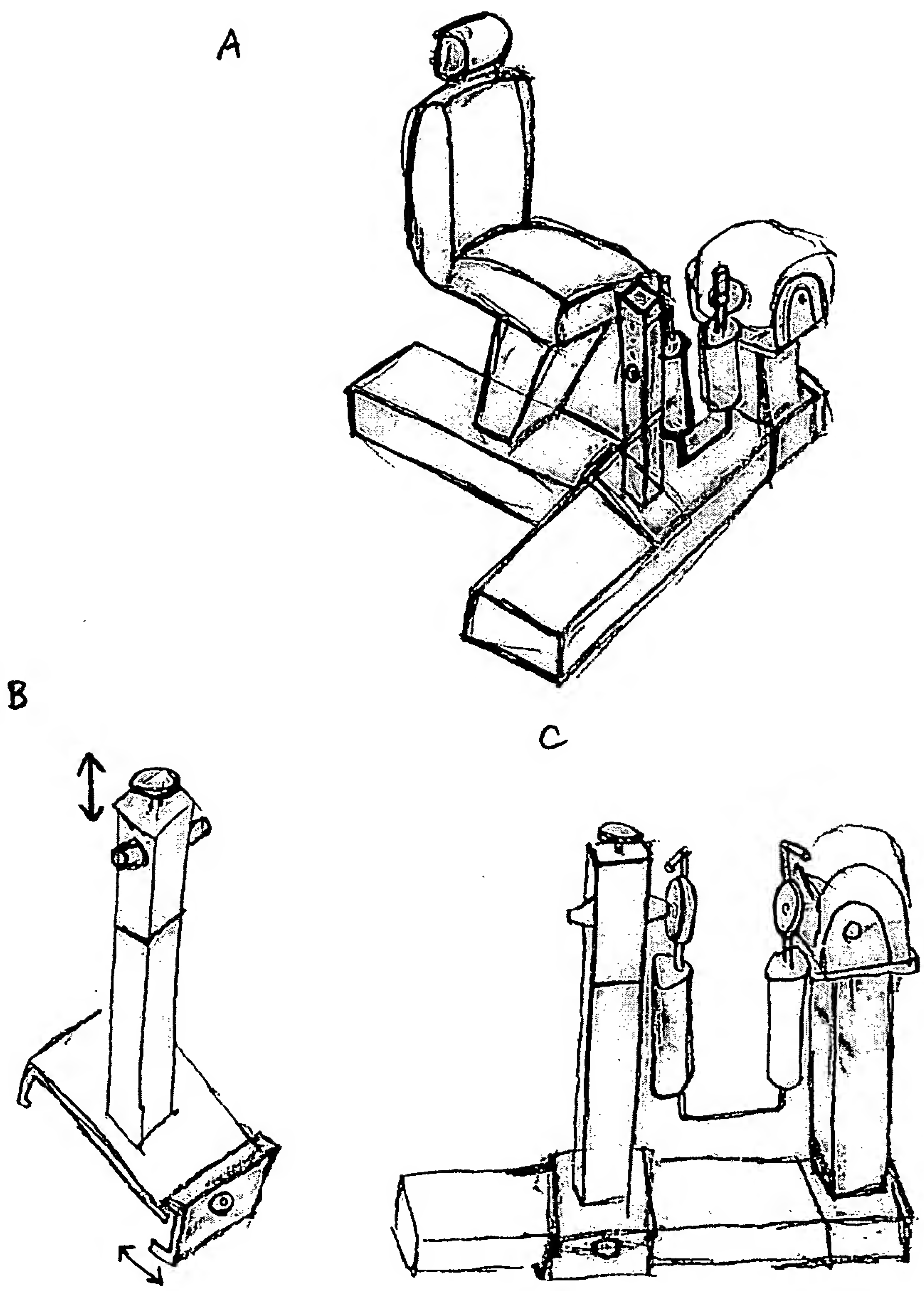
Fig 9.



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